

INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

02 FEB 2005

REC'D 13 DEC 2004

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Applicant's or agent's file reference JB02370-3/JH		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/03384	International filing date (day/month/year) 04.08.2003	Priority date (day/month/year) 02.08.2002	
International Patent Classification (IPC) or both national classification and IPC C12N9/24			
Applicant KLENZYME LTD. et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
 - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☒ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 13.05.2004	Date of completion of this report 10.12.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Loubradou, G Telephone No. +49 89 2399-8543



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1. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-13 as originally filed

Claims, Numbers

1-24 as originally filed

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 1-3, 7-10, 14-24 (partially), 6, 13 (completely)

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
☒ no international search report has been established for the said claims Nos. 1-3, 7-10, 14-24 (partially), 6, 13 (completely)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the Standard.
☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

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☐ complied with.

☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-3, 7-10, 14-24, (partially), 5 and 12 (completely) .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-3, 5, 7-9, 18, 19, 23, 24
	No: Claims	10, 12, 14-17, 21, 22
Inventive step (IS)	Yes: Claims	1-3, 5, 7-9, 18, 19
	No: Claims	10, 12, 14-17, 21-24
Industrial applicability (IA)	Yes: Claims	1-3, 5, 7-10, 12, 14-24
	No: Claims	

2. Citations and explanations

see separate sheet

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Reference is made to the following documents:

- D1: GB-A-2 325 241 (NENE COLLEGE OF HIGHER EDUCATI ;UNIV WESTMINSTER (GB)) 18 November 1998 (1998-11-18)
- D2: GHOSH M ET AL: "PRODUCTION OF EXTRACELLULAR ENZYMES BY TWO PLEUROTUS SPECIES USING BANANA PSEUDOSTEM BIOMASS" ACTA BIOTECHNOLOGICA, AKADEMIE VERLAG, BERLIN, DE, vol. 18, no. 3, 1998, pages 243-254, XP009010790 ISSN: 0138-4988
- D3: SETHURAMAN A ET AL: "PLANT-CELL-WALL-DEGRADING ENZYMES PRODUCED BY THE WHITE-ROT FUNGUS CERIPORIOPSIS SUBVERMISPORA" BIOTECHNOLOGY AND APPLIED BIOCHEMISTRY, ACADEMIC PRESS, US, vol. 27, no. 1, 1998, pages 37-47, XP009010791 ISSN: 0885-4513
- D4: PUNIYA ANIL K ET AL: "Determination of enzyme activities of lignocellulolytic strains in solid substrate fermented products" INDIAN JOURNAL OF ANIMAL NUTRITION, vol. 12, no. 4, 1995, pages 205-212, XP001179864 ISSN: 0970-3209
- D5: TONON F ET AL: "NITROGEN AND CARBON REGULATION OF LIGNIN PEROXIDASE AND ENZYMES OF NITROGEN METABOLISM IN PHANEROCHAETE-CHRYSPORIUM" EXPERIMENTAL MYCOLOGY, vol. 14, no. 3, 1990, pages 243-254, XP009026654 ISSN: 0147-5975

Re Item IV

Lack of unity of invention

- 1- The International Search Report has been drawn up in respect of claims 1-3 (partially), 4-5 (completely), 7-10 (partially), 11-12 (completely), 14-24 (partially) (inventions 1 and 4 as defined in the International Search Report). In accordance with the ISA, the IPEA finds that the subject-matter covered by the International Search Report does not comply with the requirement of unity of invention (Article 34(3) and Rules 13 and 68 PCT).
- 2- The subject-matter covered by the International Search Report is considered to lack unity of invention since said subject-matter relates not to one but rather to two separate inventions not linked together by a common underlying inventive concept. The claims and the inventions to which they relate may be grouped as

follows:

1. Claims 1-3, 7-10, 14-24 (partially), 4 and 11 (completely)
Compositions comprising a xylanase, a cellulase, a ligninase and a protease and methods using said compositions
2. Claims 1-3, 7-10, 14-24 (partially), 5 and 12 (completely)
Compositions comprising a xylanase, a cellulase, a ligninase and a uricase and methods using said compositions
- 3- An international application must relate to one invention or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. Special technical features are such features that define the contribution of the claimed invention over the prior art.

The technical features shared by the presently claimed methods and compositions are enzymes compositions comprising at least a cellulase, a xylanase, and a ligninase. However, said technical features are not novel. D1 discloses compositions comprising a laccase, a cellulase and a xylanase which are used to remove dungs from animal hides (see the example 4, page 7). D2 discloses the liquid culture of two pleurotus species using banana pseudostem biomass. The culture medium comprises at least a laccase, a xylanase and a cellulase and said medium is able to degrade banana pseudostem biomass (see pages 248 to 250 and figures 2 to 4). D3 discloses compositions comprising at least a xylanase, a cellulase, a laccase and a protease (see from page 40 the paragraph entitled "cellulolytic activities" to page 43 the paragraph entitled "Other enzymes activities"). Said compositions are obtained from the white-rot fungus *Ceriporiopsis subvermispora* and are used to degrade various lignocellulosic materials (see page 38 the paragraph entitled "Enzymes production in shake-flask cultures"). Therefore the IPEA is of the opinion that there is no single unifying inventive concept underlying the entire group of claims of the present application as required by Rule 13 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial

applicability; citations and explanations supporting such statement

4. As requested by the applicant, the examination is carried out in respect of the alleged second invention, i.e. claims 1-3, 7-10, 14-24 (partially), 5 and 12 (completely) (Compositions comprising a xylanase, a cellulase, a ligninase and a uricase and methods using said compositions).
5. D4 discloses culture conditions wherein cellulase, xylanase and laccase activities from *Phanerochaete chrysosporium* are expressed (see tables 1 and 2 of D4 and the abstract).
D4 did not study uricase activity, however it appears that *P. chrysosporium* is also able to express a uricase. Said uricase is subjected to nitrogen repression but it is detected in all the medium conditions tested in D5 (see D5, the abstract and the Tables 3 and 4). Therefore, it appears that a uricase is also inherently present in the culture conditions tested in D4.
Therefore, claims 10, 12 and 14 are not novel (Article 33.2 EPC).
Claims 15 to 17 and 20 to 22 are also considered to be anticipated by D4 since the presence in the growth medium of a specific component is not sufficient to distinguish the enzyme mixture of claim 15 from the enzyme mixtures of D4. It can be noted that the enzyme composition of claims 15 to 17 and 20 to 22 can correspond to any composition comprising a uricase, cellulase, xylanase and ligninase obtained from *P. chrysosporium* since the enzyme composition of claims 15 to 17 and 20 to 22 **comprises** an enzyme mixture obtained under certain conditions but may also comprise any other enzyme or enzyme composition in any proportion.
Claims 23 and 24 correspond to obvious embodiments which cannot involve an inventive activity (Article 33.3 PCT).
6. None of the cited documents discloses or suggests to use a composition comprising a uricase, a cellulase, a xylanase and a ligninase in order to solubilise or decompose bird droppings, therefore claims 1 to 3, 5 and 7 to 9 (as far as they are restricted to methods using a composition comprising a uricase, a cellulase, a xylanase and a ligninase) are considered to be novel and to involve an inventive activity (Articles 33.2 and 33.3 PCT).
In absence of documents showing that fungi selected from the species *Coriolus*, *Pleurotus* and *Ganoderma* have been cultivated in the prior art under conditions which allow the expression of at least a cellulase, xylanase, laccase and uricase,

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claims 18 and 19 (as far as they are restricted to compositions comprising at least a uricase, a cellulase, a xylanase and a ligninase) are considered to be novel and to involve an inventive activity (Articles 33.2 and 33.3 PCT).